

REMARKS

Review and reconsideration of the Office Action of April 18, 2007, is respectfully requested in view of the above amendments and the following remarks.

No new matter has been added to the claims or the specification.

Status of the Claims

Claims 1-5 and 7-22 were pending.

Independent claims are amended to recite that the synergistic antimicrobial effect is attributed to the combination of the 1,2-alkanediols. This being the essence of the invention, support for the amendment can be found throughout the specification.

Status of Claim 8: In the Office Action of August 15, 2006 claim 8 was examined. In Amendment C claim 8 was amended to a method claim. In the Office Action of April 18, 2007 the Examiner indicates that claim 8 is withdrawn. However, the Examiner did not pose any Restriction Requirement setting forth grounds for restriction and affording Applicants the opportunity to traverse. In the interests of expedited examination, Applicants herewith revert claim 8 to a product claim, claim 8 distinguishing over claim 1 by use of the limitation "consisting of". Accordingly, it is submitted that claim 8 is in condition for examination.

Accordingly, it is submitted that claims 1-5 and 7-22 are in condition for examination.

Summary

The present invention is based on the discovery of unexpected synergistic effects observed in antimicrobial compositions comprising two or more straight-chain 1,2-alkanediols having different chain lengths in the range of 5 to 10 C atoms.

In the "Response to Arguments" the Examiner considers the invention obvious over

- mixtures: Clarkson teaching combinations of alkanediols (as "solubility promoters", not antimicrobial agents) and Cupferman et al disclosing mixtures of at least one polyol (without however recognizing any synergism attributable to any combination of polyols), and

{WP418947;1}

- synergism: Cupferman et al teaching synergistic antimicrobial action (of alkanediols with other antimicrobial agents, but never merely with combinations of alkanediols).

It appears that the Examiner considers that

- if there is known synergism between polyols and one specific non-polyol,
- then the simple addition of different polyols to this mixture would result in a mixture which still exhibits synergism,
- the claims read on synergism with mixtures of polyols even if this synergism might be attributable to other (non-polyol) antimicrobial agents as taught in Cupferman et al.

Applicants submit that this has nothing to do with the present invention, but to clarify the claims and to clearly distinguish over the above combination of teachings, Applicants amend the claims to recite that the synergistic antimicrobial effect is attributed to the combination of 1,2-alkanediols.

The claims thus distinguish over prior art teaching synergism between (a) alkanediols (alone or in combination) and (b) non-alkanediols, i.e., a synergism not achieved without the non-alkanediols.

It is thus believed that all claims are now in condition for allowance.

Office Action

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Claim Rejections – 35 U.S.C. §103

Claims 1-5,7-19 are rejected under 35 U.S.C. §103 (a) as being obvious over Clarkson et al. (U.S. Patent Application 2001/0036964 A1) in view of Eggensperger et al. (U.S. Patent 5,670,160) and further in view of Riebel et al. (U.S. Patent Application 2003/0100613A1).

The basic position of the Examiner is that, where the prior art teaches anti-microbial action of alkyldiols, the synergistic effect of combinations of alkyldiols would be obvious.

Applicants respectfully traverse.

{WP418947;1}

Clarkson et al

Applicants first point out that in Clarkson et al U.S. Patent Application 2001/0036964 A1, the **alkanes (and their mixtures)** are merely described as "**solubility promoter**", but not as antimicrobial agents, thus this reference can not be combined with Cupferman.

More specifically, Clarkson et al teach an antimicrobial comprising

- (i) a C.sub.1 to C.sub.4 monohydric alcohol carrier fluid, present at a level of at least 25% by weight of the total composition (excluding any volatile propellant present);
- (ii) an iron (III) chelator having an iron (III) binding constant of 10.sup.23 or greater;
- (iii) a solubility promoter selected from the group consisting of: (a) water; (b) an organic amine; (c) **a polyhydric alcohol** or derivative thereof; (d) a volatile propellant having fluorine-carbon or oxygen-carbon bonds; (e) any combination of (a) to (d).

The mere presence of polyhydric alcohol in an antimicrobial composition provide no suggestion of the present invention, i.e., synergistic effects of synergistic effects of combinations of different straight-chain 1,2-alkanediols with a chain length in the range of 5 to 10 C atoms

Cupferman et al

Cupferman et al at best teach that

- (a) it is permissible to use combinations of polyols (though no examples are given), and
- (b) there is synergism when using a polyol in combination with one of
 - green tea,
 - sodium capryl lactyl lactylate and
 - Hinokitiol.

See Cupferman et al paragraph [0073] following the examples:

"These tests demonstrate the existence of synergism between [either of (a)] the two polyols tested [separately] and [(b)] green tea, sodium capryl lactyl lactylate and Hinokitiol. The simultaneous use of a polyol and of one of the three abovementioned compounds in a cosmetic formulation makes it possible to obtain a protection against bacteria and fungi without encountering the skin tolerance problems associated with the use of conventional chemical preserving agents or a high proportion of polyols.

1. That is, Cupferman et al only tested two polyols, 1,2-octanediol and 1,2-pentanediol, and in each case used only one polyol at a time in combination with one other ingredient.

2. Cupferman et al never teach synergism between two polyols, so we may presume all are equivalents and if mixed would produce only the expected additive, not multiplicative, effect.

3. Cupferman et al do not teach specific polyols with which there is synergism.

Cupferman et al does not teach the present specific limited group of polyols capable of producing a synergistic effect. The present polyols are 5-10C. Cupferman et al teaches an antimicrobial comprising:

(I) - at least one polyol selected from the group consisting of polyols comprising 4 to 8 carbon atoms, or

- mono (C₃-C₉) alkyl, or
- (C₃-C₉) alkenyl glyceryl ethers; and

(II) 2-hydroxy-4-(1-methylethyl)cyclohepta-2,4,6-trien-1-one .

So, to get from Cupferman to the present invention it would be necessary to:

(a) find some motivation to search for synergistic combinations of agents not including 2-hydroxy-4-(1-methylethyl)cyclohepta-2,4,6-trien-1-one (Cupferman et al provide no such motivation)

(b) conduct much experimentation in search for synergism with:

- combinations of polyols,
- combinations of mono (C₃-C₉) alkyls,
- combinations of (C₃-C₉) alkenyl glyceryl ethers,
- combinations of polyols and mono (C₃-C₉) alkyls,
- combinations of polyols and (C₃-C₉) alkenyl glyceryl ethers,

- combinations of polyols and (C₃-C₉) alkenyl glyceryl ethers, and
- combinations of polyols, mono (C₃-C₉) alkyls, and (C₃-C₉) alkenyl glyceryl ethers,

and upon discovering synergistic effects in combinations of polyols, identify the end-points of the C# range.

So, the present invention is a long way from Cupferman et al and this reference provides no teaching leading to the present invention.

In fact, considering the comprehensive research of record on the antimicrobial activity of individual diols having a chain length in the range of 5 to 10 C atoms, it must be seen as particularly **surprising** that mixtures of two, three or more straight-chain 1,2-alkanediols, the chain lengths of which (i) are difference and (ii) in each case are in the range of 5 to 10 C atoms display **a strongly synergistic activity and are clearly superior** to the individually dosed 1,2-diols having chain lengths in the same range in the same concentration, in particular with regard to the reduction in germ time. In particular, a CFU value (CFU = number of colony-forming units) of 0 can be achieved in the individual case only with the said mixtures according to the invention.

The present specification provides extensive evidence of the unexpected strong synergism found with the claimed combinations. See particularly K values in the right column of Table 7.

Accordingly, Applicants have demonstrated the surprising synergistic enhanced antimicrobial activity commensurate in scope with the claims. This synergism is not suggested in Clarkson. The Examiner is also requested to note that there is no clear dependence between the chemical structure of a substance, on the one hand, and its biological activity towards specific microorganisms (germs) and its stability, on the other hand. Furthermore, there is no predictable relationship between the antimicrobial action, toxicological acceptability, tolerance by the skin and the stability of a substance. This further supports the unexpected nature of the surprising finding that straight-chain 1,2-alkanediols with a chain length in the range of 5 to 10 C atoms

exhibit a **synergistically intensified** antimicrobial effect, at least against selected germs, if they are combined with a second or further straight-chain 1,2-alkanediols with different chain lengths in the same range.

Finally, turning to the Examiner's specific comments, the Examiner refers to paragraph [0008] of Cupferman et al.:

Thus, after considerable research conducted in this matter, the Applicant has now discovered, surprisingly and unexpectedly, that a antimicrobial agent comprising a specific polyol combined with 2-hydroxy-4-(1-methylethyl) cyclohepta-2,4,6-trien-1-one or sodium capryl lactyl lactylate has high and synergistic antimicrobial action, thereby preserving compositions into which it is introduced.

It is clear from the above discussion that the Examiner mis-interprets this paragraph. First, synergism is limited to combinations of (a) a specific polyol **with** (b) at least one specific non-polyol. The cited paragraph specically teaches that, absent 2-hydroxy-4-(1-methylethyl) cyclohepta-2,4,6-trien-1-one or sodium capryl lactyl lactylate, there is no synergism. So, the paragraph can not be interpreted in the manner suggested by the Examiner.

Eggensperger et al, Riebel and Clarkson

Turning finally to the secondary references, Eggensperger et al and Riebel et al are not cited for teaching combinations of straight-chain 1,2-alkanediols with a chain length in the range of 5 to 10 C atoms, but rather merely the use of supplemental antimicrobial agents.

Riebel et al is merely cited for teaching:

The ready-to-use compositions can also comprise other insecticides, if appropriate, and also one or more fungicides, if appropriate.

... fungicides, such as epoxyconazole, hexaconazole, azaconazole, propiconazole, tebuconazole, cyproconazole, metconazole, imazalil, dichlorfluanid, tolyl-fluanid, 3-iodo-2-propinyl-butyl carbamate, N-octyl-isothiazolin-3-one and 4,5-di-chloro-N-octylisothiazolin-3-one.

So, Reibel et al merely teach that one of the preservatives listed in our claim 12 is a known preservative.

Applicants would concede that one or more of the preservatives listed in claim 12 are not novel. However, claim 12 is merely a dependent claim, and depends from claim 11 (two or more diols), in which the invention is recited.

Thus, claim 12 is allowable by virtue of dependency from claim 11, and for this reason Reibel et al is not relevant prior art.

Eggensperger et al is similar to Reibel et al, and the same counter argument can be used, thus there is no need to rely on priority.

Turning finally to Clarkson, xtensive technical and legal arguments against Clarkson et al. were presented in Amendment A.

The Examiner's "Response to Arguments"

The Examiner

- relies on the prior art as teaching synergism in mixtures, which mixtures may include combinations of diols, but the synergism being attributable to the addition of other, non-diol antimicrobial agents, and

- takes a secondary position that if Cupferman et al teaches only the combination of one diol and either 2-hydroxy-4-(1-methylethyl)cyclohepta-2,4,6-trien-1-one or sodium capryl lactyl lactylate, "the claims would still be rejected because it is obvious to combine two compositions used for the same purpose, which is for inhibiting the growth of microorganisms."

"It is prima facie obvious to combine two compositions ... useful for the same purpose, in order to form a third composition to be used for the very same purpose..."

However, the Examiner here

- completely disregards that the USPTO has found synergism to be patentable,
- completely ignores Applicants' data regarding synergism,
- disregards that the prior art provides no teaching of synergism in combinations of diols, despite extensive research, and

- disregards that the prior art requires additional essential active ingredients which are not relevant to the present discovery of synergism with combinations of diols.

Request Withdrawal of Finality

Requesting withdrawal of the finality of the Office Action in view of the new reference cited by the Examiner.

Request Telephone Interview

A Form PTO-413A is attached, requesting a Telephone Interview August 13, 2007 at 2:00 PM.

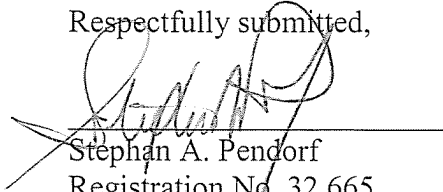
Accordingly, it is respectfully submitted that the claims as amended are in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 50-0951.

Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,

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